an intermediate clinical endpoint that was considered reasonably likely to predict the drug's clinical benefit.

As a condition of MAKENA's approval, the sponsor was required to complete a postmarketing trial to verify and describe the clinical benefit of MAKENA in reducing neonatal morbidity and mortality from complications of PTB among babies born to women with a singleton pregnancy who had a previous singleton sPTB. This postmarketing confirmatory trial, Trial 003, failed to show that MAKENA reduced the risk of neonatal morbidity and mortality from complications of PTB and failed to show a treatment effect of MAKENA on the intermediate clinical endpoint that was the basis of MAKENA's approval.

On October 5, 2020, CDER issued a proposal to withdraw approval of MAKENA and a notice of opportunity for hearing (NOOH) on two independent grounds using expedited procedures under section 506(c)(3) of the FD&C Act and 21 CFR 314.530(a): (1) the confirmatory trial failed to verify the clinical benefit of the drug and (2) the evidence demonstrates that the drug is not shown to be effective under its conditions of use. CDER's NOOH and proposal to withdraw approval of MAKENA also provided notice to all holders of approved ANDAs referencing the NDA for MAKENA (NDA 021945) that, if the Agency were to withdraw approval of MAKENA, CDER would withdraw approval of those ANDAs under 21 CFR 314.151(b)(3).

MAKENA's sponsor submitted a hearing request dated October 14, 2020, followed by a submission of data and information in support of the hearing request. The Agency granted the sponsor's hearing request on August 18, 2021, and on August 17, 2022, published a notice of hearing (87 FR 50626). The hearing was held on October 17, 18, and 19, 2022. The Obstetrics, Reproductive and Urologic Drugs Advisory Committee was present at the hearing to review the issues involved and to provide advice and recommendations to the Commissioner. The presiding officer issued a report, dated January 19, 2023, that summarized the legal and factual background, content of the hearing, and her analysis and recommendations. On April 6, 2023, after considering CDER's and Covis' March 6, 2023, post-hearing submissions, the Commissioner and Chief Scientist jointly issued a final decision withdrawing approval of MAKENA and the ANDAs that referenced MAKENA.

FDA has withdrawn approvals of the following NDA and eight ANDAs:

Application No.	Drug	Holder/sponsor
NDA 021945	Makena (hydroxyprogesterone caproate) Injection, 250 mg per mL	Covis Pharma Group/Covis Pharma GmbH.
ANDA 208381	Hydroxyprogesterone Caproate Injection USP, 250 mg/mL	Sun Pharmaceutical Industries, Ltd.
ANDA 210618	Hydroxyprogesterone Caproate Injection USP, 250 mg/mL	Slayback Pharma LLC.
ANDA 210723	Hydroxyprogesterone Caproate Injection USP, 250 mg/mL	American Regent, Inc.
ANDA 210724	Hydroxyprogesterone Caproate Injection USP, 250 mg/mL	Do.
ANDA 210877	Hydroxyprogesterone Caproate Injection USP, 250 mg/mL	Slayback Pharma LLC.
ANDA 211070	Hydroxyprogesterone Caproate Injection USP, 250 mg/mL	Eugia Pharma Specialities Ltd.
ANDA 211071	Hydroxyprogesterone Caproate Injection USP, 250 mg/mL	Do.
ANDA 211777	Hydroxyprogesterone Caproate Injection USP, 250 mg/mL	Aspen Pharma USA Inc.

Withdrawal of approval of the applications listed in the table includes all strengths, dosage forms, amendments, and supplements to these applications, effective April 6, 2023. As discussed in the decision of the Commissioner and Chief Scientist, FDA has withdrawn approval of the MAKENA NDA for reasons of safety or effectiveness, as well as approval of the ANDAs that reference MAKENA.

Section 505(j)(7) of the FD&C Act (21 U.S.C. 355(j)(7)) requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book,'' available at *https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.* Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness 21 CFR 314.162. Accordingly, the Agency has removed the applications listed in the table from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that reference MAKENA.

II. Electronic Access

Persons with access to the internet may obtain the final decision at *https://downloads.regulations.gov/FDA-2020-N-2029-0385/attachment_1.pdf.* The final decision, a transcript of the hearing, and other documents pertaining to the withdrawal of the NDA for MAKENA (NDA 021945) are available at *https://www.regulations.gov* under the docket number found in brackets in the heading of this document.

Dated: May 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10264 Filed 5–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1905 and FDA–2020–E–1896]

Determination of Regulatory Review Period for Purposes of Patent Extension; Tack Endovascular System (6F)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Tack Endovascular System (6F) and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that medical device.

DATES: Anyone with knowledge that any of the dates as published (see

SUPPLEMENTARY INFORMATION) are incorrect must submit either electronic or written comments and ask for a redetermination by July 14, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 13, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 14, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2020–E–1905 and FDA–2020–E–1896 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; TACK ENDOVASCULAR SYSTEM (6F).'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device Tack Endovascular System (6F). Tack Endovascular System (6F) is indicated for use in the superficial femoral and proximal popliteal arteries ranging in diameter from 3.5 millimeters (mm) to 6.0 mm for the repair of post percutaneous transluminal balloon angioplasty dissection(s). Subsequent to this approval, the USPTO received patent term restoration applications for Tack Endovascular System (6F) (U.S. Patent Nos. 9,375,327 and 9,603,730) from INTACT VASCULAR, INC., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated November 9, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of Tack Endovascular System (6F) represented the first permitted commercial

marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Tack Endovascular System (6F) is 1,338 days. Of this time, 1,114 days occurred during the testing phase of the regulatory review period, while 224 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* August 14, 2015. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) for human tests to begin, as required under section 520(g) of the FD&C Act, became effective August 14, 2015.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 31, 2018. FDA has verified the applicant's claim that the premarket approval application (PMA) for Tack Endovascular System (6F) (PMA P180034) was initially submitted August 31, 2018.

3. *The date the application was approved:* April 11, 2019. FDA has verified the applicant's claim that PMA P180034 was approved on April 11, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 485 days or 621 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10297 Filed 5–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1703]

Determination That CATAPRES (Clonidine Hydrochloride) Tablets, 0.1 Milligrams; 0.2 Milligrams; and 0.3 Milligrams, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 017407	CATAPRES	Clonidine Hydrochloride	0.1 Milligrams (mg); 0.2 mg; 0.3 mg	Tablet; Oral	Boehringer Ingelheim.
NDA 017534	FIORINAL	Aspirin; Butalbital; Caffeine.	325 mg; 50 mg; 40 mg	Capsule; Oral	Allergan Sales.